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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,826	08/13/2002	Mark J. Pykett	C01005/70008	5264

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N	Applicant(s)	
	10/088,826	PYKETT ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6-8, and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9-16 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/28/04;09/30/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-16 and 18-21 are pending.

1. Applicant's election with traverse of Group II, claims 1-3, 5, 9-16 and 18-20 and tantalum as species of metal and bFGF as species of growth factor to produce neuronal cells in the reply filed on 12/08/2004 is acknowledged. Applicant traverse the Restriction Requirement on the grounds that the inventions must be both independent and distinct and an undue search burden on the examiner and that search of claims of group II would provide usefull information for at least Groups I and V. However, MPEP 803 states that the Inventions be either independent or distinct and a burden on the Examiner if restriction is required.

Regarding applicant's comments about undue burden, the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criteria, indicates that inventions recognized divergent subject matter and that a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. All the above establishes that serious burden is placed on the examiner by the examination of more than one Group. The Inventions are distinct for reasons elaborated in the previous Office Action and above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 6-8, and 21 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-3, 5, 9-16 and 18-20 reads on a method for in vitro culture of hematopoietic progenitor cells to produce differentiated cells, wherein differentiated cells are neuronal cells and wherein growth factor is bFGF and wherein solid matrix is tantalum-coated are under consideration in the instant application.

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2. Claim 5 is objected to because of the following informalities: the word "cells" in line 4 is misspelled .

Appropriate correction is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-3,5,9-16 and 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by WO9915629.

WO' 629 teaches a method for in vitro culture of hematopoietic progenitor cells to produce differentiated cells of non-hematopoietic lineage (see entire document, Abstract in particular). WO'629 teaches that said cells are cultured under condition that promote differentiation, using three dimensional porous matrix having a unitary microstructure having a percent of open space of at least 75% and having a diameter of pores at mid-point on average of less than 150 μm (see page 5 lines 12 in particular). WO'629 teaches that porous solid matrix is a metal-coated wherein a metal is tantalum (see page 5, lines 10-25 in particular).). WO' 629 teaches porous solid matrix having seeded hematopoietic progenitor cells wherein said cells is impregnated with a gelatinous agent that occupies pores of the matrix (see pages 8-9 in particular). WO' 629 teaches that hematopoietic progenitor cells are obtained from blood product wherein blood product is unfractionated bone marrow (see pages 5 and 26 in particular). WO' 629 teaches that hematopoietic progenitor cells are $\text{Cd}34^+$ or $\text{CD}34^+$ or can be isolated from nonnucleated cells or enriched for cells having a common marker (see examples 1-4 in particular). WO' 629 teaches that hematopoietic progenitor cells are cultured in the presence of various growth factor that promote differentiation such as bFGF (see pages 6 and 12 in particular). It is noted that WO' 629 teaches does not explicitly disclosed that under recited conditions hematopoietic progenitor cells would produce neuronal cells. However, the recited conditions, i.e. culturing hematopoietic progenitor cells in the environment comprising bFGF is the same condition as claimed (see instant claim 5 in particular). Thus a method taught by WO' 629 would inherently result in producing neuronal cells. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, i.e. culturing hematopoietic progenitor cells in an environment comprising three dimensional porous matrix and comprising growth factor bFGF, it can be assumed the method will inherently perform the claimed process, i.e produce neuronal cells. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue

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Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)

The reference teaching anticipates the claimed invention.

5. No claim is allowed.


6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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January 19, 2005


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